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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,232	07/22/2003	Nagy Adly Habib	380048-97	8627

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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
03/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,232	HABIB ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35 and 37-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/01/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the two by two array of needles must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-35 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Presently, the explicit recitations of a two by two array of needles are not supported by the specification.

Claims 3-18, 21-23 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Presently, the explicit recitations of "approximately 10 millimeters in" from claim 3 is not supported by the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 12-19 and 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (U.S. Patent 5,472,441) in view of Edwards (U.S. Patent 5,836,906) in still further view of Swanson (U.S. Patent 6,267,760) and still in further view of Lennox et al. (U.S. Patent 5,919,191).

Regarding claims 1-6, 12-14, 19 Edwards et al. disclose a device and method of treating tissue and/or an organ, the method comprising providing a device, the device comprising an applicator (222) having at least one face including an array of needles (215-219) each needle including a tissue-piercing distal tip (tissue piercing means), said array of needles arranged on said at least one face (distal face of 222 from through the needles pass) of the applicator, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of needles so that said array of needles surround a volume of tissue of tissue to be treated, said array of needles serving to confine the electromagnetic energy field; extending the tissue-piercing distal tips of said array of needles from said at least one face of said applicator into said volume of tissue to

be treated; applying said electromagnetic energy confined by the needles to the volume of the tissue to be treated; removing the tissue piercing distal tips of said array of needles from the volume of tissue to be treated, see 1-13 and more particularly col. 2, col.6-8 and col. 13, lines 53-60 and figures 1-16 and figure 16 in particular. It should be noted the mere application of electromagnetic energy to the tissue by the needle array creates a heat-treated tissue volume (having a desired length, width and depth). Edwards et al. clearly disclose at least two needles which define a radiation pattern having a localized power profile/distribution centered on the needles, which is interpreted as confining the heat-treated tissue volume (which coincides with the power profile/distribution), see 1110 of figure 11. Additionally, having the heat-treated tissue volume center coincide with the planned incision line is extremely well known and desirable, as the heat-treated tissue volume center/line of center is the point/line of maximum symmetry and therefore the best location to place the incision. Edwards et al. fail to explicitly disclose that the method is used to reduce bleeding and/or blood loss. Edwards et al. fail to explicitly disclose use of microwave but do disclose the known use on microwave energy to treat the tissue with the use of a cooling fluid to prevent undue damage, see col. 1, line 65 through col. 2, line 25. Additionally, Edwards et al. fail to explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. Edwards et al. explicitly disclose "high-frequency currents are used in electrocautery procedures for cutting human tissue, especially when a bloodless incision is desired or when the operating site is not accessible with a normal scalpel but presents an access for a thin

instrument through natural body openings such as the esophagus, intestines or urethra. Examples include the removal of prostatic adenomas, bladder tumors or intestinal polyps. In such cases, the high-frequency current is fed by a surgical probe into the tissue to be cut. The resulting dissipated heat causes boiling and vaporization of the cell fluid at this point, whereupon the cell walls rupture and the tissue is separated. The frequency of the current for this use must be above ca. 300 kHz in order to avoid any adverse nerve and/or muscle responses," see col. 1:42-55. Additionally, Applicant discloses on page 1, lines 10-15 that it is well known that heating tissue 20°C – 30°C greatly reduces blood flow. This great reduction in blood flow provides the inherent control of blood loss when tissue is heated. Edwards discloses a tissue heating device having retractable needles (12) and teaches an alternative or equivalent energy delivery of microwave with cooling means and RF, see col. 1-7 and particularly col. 7, lines 28-38 and figures 1-6. Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue, see col. 8, lines 33-41. Lennox et al. disclose an electrosurgical device for tissue removal and teach coagulating tissue prior to resection in order "to effect substantially bloodless tissue removal which can reduce complications from blood loss, fluid absorption, time in surgery, and patient trauma," see col. 4:12-32. The present combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line. Additionally, the examiner interprets "bloodlessly resecting the tissue from the body" as broadly equivalent to "severing the tissue from the body" without excessive bleeding. Therefore at the time of

the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al., as taught by Edwards, to use microwave (electromagnetic) energy as an alternate means of heating tissue, and as is well known in the art, that blood flow in tissue is greatly reduced if the tissue is heated 20°C – 30°C, and as taught by Swanson, to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue, and as is also well known to place the incision line at the center/line of center of the heat-treated tissue volume since that is the point/line of maximum heat-treated tissue volume symmetry and as finally taught by Lennox et al., to coagulate the tissue sufficiently in order to resect (sever from the body) the tissue bloodlessly. **Additionally, it should be noted the recited "width" is incredibly broad and consequently inherently met by the Edwards et al. patent as a grid pattern has at least one channel having a width, which meets the recited subject matter. With regard to the needles being "energizeable together", without a recitation of the essential elements conducting wires and a generator programmed and configured to energize the electrodes together, this recitation is one lacks essential elements. Futhermore. Edwards et al. disclose a system wherein the electrodes are energized simultaneously/together, see col. 13:15-52. Additionally, the "grid pattern" of Edwards et al. includes a minimal grid pattern having four needles in two rows and two columns, wherein the needles are located at the corners. It should be noted, this rectangular grid pattern has no interior needles therewithin. Lacking an explicitly recitation of this minimal grid pattern having only four needles in two rows and two columns it would be obvious to one of ordinary skill in**

the art to provide a grid pattern of needle electrodes in a 2x2 array, since it would be obvious to try the 2x2 grid pattern since it is the simplest and smallest of the grid patterns. Finally, lacking an explicitly recitation of this minimal grid pattern having "four rows of needles of two needles each," it would be obvious to one of ordinary skill in the art to provide the device with a four-by-two array of needles as it is merely a design choice, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Additionally, pending a statement of criticality, one grid pattern of needle electrodes is treated as alternate/equivalent to another grid pattern of needle electrodes. Finally, Swanson discloses the resection/removal of diseased liver lobes, see col. 45:19-52.

Regarding claims 15-18, 28-31 and 33-35, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention, see Edwards et al. col. 6-14 and figure 16.

Regarding claims 25-27, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention, see Edwards et al. figures 1-16.

Regarding claim 32, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention, see the conducting wires connected to the needles of (Edwards I) in figures 1-16.

Claims 7-11 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (U.S. Patent 5,472,441) in view of Edwards (U.S. Patent 5,836,906) in still further view of Swanson (U.S. Patent 6,267,760) and still in further view of Lennox et al. (U.S. Patent 5,919,191) as applied to claims 1, 3 and 6 above, and still further in view of admitted prior art.

Regarding claims 7-11 and 20-24 Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention in further view of Applicant's admission on the record that the claimed species are not patentably distinct as noted above.

Claims 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (U.S. Patent 5,472,441) in view of Swanson (U.S. Patent 6,267,760) and further in view of Lennox et al. (U.S. Patent 5,919,191).

Regarding claims 37 and 40, Edwards et al. disclose a device and method of treating tissue and/or an organ, the method comprising providing a device, the device comprising an applicator (222) having at least one face including an array of needles (215-219) each needle including a tissue-piercing distal tip (tissue piercing means), said array of needles arranged on said at least one face (distal face of 222 from through the needles pass) of the

applicator, said applicator structured to be operably coupled to a source of electromagnetic energy; positioning said array of needles so that said array of needles surround a volume of tissue of tissue to be treated, said array of needles serving to confine the electromagnetic energy field; extending the tissue-piercing distal tips of said array of needles from said at least one face of said applicator into said volume of tissue to be treated; applying said electromagnetic energy confined by the needles to the volume of the tissue to be treated; removing the tissue piercing distal tips of said array of needles from the volume of tissue to be treated, see 1-13 and more particularly col. 2, col.6-8 and col. 13, lines 53-60 and figures 1-16 and figure 16 in particular. It should be noted the mere application of electromagnetic energy to the tissue by the needle array creates a heat-treated tissue volume (having a desired length, width and depth). Edwards et al. clearly disclose at least two needles which define a radiation pattern having a localized power profile/distribution centered on the needles, which is interpreted as confining/defining the heat-treated tissue volume (which coincides with the power profile/distribution), see 1110 of figure 11. Edwards et al. fail to explicitly disclose use of microwave but do disclose the known use on microwave energy to treat the tissue with the use of a cooling fluid to prevent undue damage, see col. 1, line 65 through col. 2, line 25. Additionally, Edwards et al. fail to disclose to explicitly disclose the step of making an incision into the tissue which has been heated and advancing the applicator and extending the tissue-piercing distal tips along an incision line. Finally, Edwards et al. fail to explicitly disclose bloodless resection of tissue. Edwards et al. explicitly disclose "high-frequency currents are used in electrocautery procedures for cutting human tissue,

especially when a bloodless incision is desired or when the operating site is not accessible with a normal scalpel but presents an access for a thin instrument through natural body openings such as the esophagus, intestines or urethra. Examples include the removal of prostatic adenomas, bladder tumors or intestinal polyps. In such cases, the high-frequency current is fed by a surgical probe into the tissue to be cut. The resulting dissipated heat causes boiling and vaporization of the cell fluid at this point, whereupon the cell walls rupture and the tissue is separated. The frequency of the current for this use must be above ca. 300 kHz in order to avoid any adverse nerve and/or muscle responses," see col. 1:42-55. Applicant discloses on page 1, lines 10-15 that it is well known that heating tissue 20°C – 30°C greatly reduces blood flow. This great reduction in blood flow provides the inherent control of blood loss when tissue is heated. Swanson discloses a device and method of heating tissue and teaches making an incision in the treated tissue after the heating step in order to reduce blood loss and verify the coagulation depth in the treated tissue, see col. 8, lines 33-41. Additionally, having the heat-treated tissue volume and/or width straddle the planned incision line is inherent, as Swanson teaches incising within the heat-treated volume. Lennox et al. disclose an electrosurgical device for tissue removal and teach coagulating tissue prior to resection in order "to effect substantially bloodless tissue removal which can reduce complications from blood loss, fluid absorption, time in surgery, and patient trauma," see col. 4:12-32. The present combination of the prior art meets the advancement of the applicator and extension of the array of needles along an incision line. Additionally, the examiner interprets "bloodlessly resecting the tissue from the body" as broadly equivalent to

"severing the tissue from the body" without excessive bleeding. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Edwards et al., as is well known in the art, that blood flow in tissue is greatly reduced if the tissue is heated 20°C – 30°C, as taught by Swanson, to make an incision in the heated tissue in order to reduce blood loss and verify the coagulation depth in the treated tissue, and as is also well known to place the incision line at the center/line of center of the heat-treated tissue volume since that is the point/line of maximum heat-treated tissue volume symmetry and as finally taught by Lennox et al., to coagulate the tissue sufficiently in order to resect (sever from the body) the tissue bloodlessly. **With regard to the needles being "energizeable together", without a recitation of the essential elements conducting wires and a generator programmed and configured to energize the electrodes together, this recitation is one lacks essential elements. Futhermore. Edwards et al. disclose a system wherein the electrodes are energized simultaneously/together, see col. 13:15-52. Additionally, the "grid pattern" of Edwards et al. includes a minimal grid pattern having four needles in two rows and two columns, wherein the needles are located at the corners. It should be noted, this rectangular grid pattern has no interior needles therewithin. Lacking an explicitly recitation of this minimal grid pattern having only four needles in two rows and two columns it would be obvious to one of ordinary skill in the art to provide a grid pattern of needle electrodes in a 2x2 array, since it would be obvious to try the 2x2 grid pattern since it is the simplest and smallest of the grid patterns. Finally, lacking an explicitly recitation of this minimal grid pattern having "four rows of**

needles of two needles each," it would be obvious to one of ordinary skill in the art to provide the device with a four-by-two array of needles as it is merely a design choice, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Additionally, pending a statement of criticality, one grid pattern of needle electrodes is treated as alternate/equivalent to another grid pattern of needle electrodes. Finally, Swanson discloses the resection/removal of diseased liver lobes, see col. 45:19-52.

Regarding claim 38, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention as the tissue heat-treating device makes an ablation lesion locally and the device must be removed so that the lesion area is free to be incised.

Regarding claim 39, Edwards et al. in view of Swanson and further in view of Lennox et al. disclose the claimed invention, see Swanson col. 8:33-41, col. 45:19-43.

Regarding claim 41, Edwards et al. disclose the claimed invention see figure 11.

Regarding claim 42, Edwards et al. disclose the claimed invention, see col. 3:11-28.

Regarding claims 43 and 44, Edwards et al. disclose the claimed invention, see col. 3 and figures 1-19.

Response to Arguments

Applicant's arguments filed 12/01/2009 have been fully considered but they are not persuasive.

Regarding Applicant's arguments/remarks on page 4 of 16, 1st full paragraph through page 5 of 16, line 5, there are several issues with the recite 2x2 array of needles. First, there are no drawings whatsoever that support this explicit recitation of 2x2 array of needles. Secondly, as Edwards et al. do explicitly recite a grid pattern, which includes an infinite number of arrays, they also disclose other different shaped patterns. Applicant's argument of an infinite number of experiments is unfounded, as one of ordinary would start with the simplest finite n by m arrays, where n and m are integers from 2 to 5. Third, there are no unexpected results obtained by Applicant when using a 2 by 2 opposed to a 3 by 2, 3 by 3, 3 by 4 and so on and so forth. With a more densely packed array the energy densities and patterns are more dense. With all due respect, this line of attack is extremely unpersuasive.

Regarding Applicant's arguments/remarks on page 5 of 16, 1st full paragraph, only Applicant is discussing linear array of needles as Edwards et al. clearly disclose a grid pattern which includes rectangular and square arrays.

Regarding Applicant's arguments/remarks on page 5 of 16, last paragraph, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Again, it is Applicant who keeps

referring to a single needle or a linear array. Applicant may wish to consider the combination as a whole.

Regarding Applicant's arguments/remarks on page 6 of 16, 1st full paragraph, as a whole lope of liver is resected and the needles penetrate the liver lope, and liver lobes are 10 millimeters or more thick, the prior art combination meets the claim.

All other arguments/remarks are refuted by the above comments.

The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

The rejections are affirmed and this action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769